



International Journal of Innovative Technologies in Social Science

e-ISSN: 2544-9435

Operating Publisher
SciFormat Publishing Inc.
ISNI: 0000 0005 1449 8214

2734 17 Avenue SW,
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Canada
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ARTICLE TITLE CENTANAFADINE IN ATTENTION-DEFICIT/HYPERACTIVITY DISORDER: PHARMACOLOGICAL INNOVATION WITHIN DIGITALLY MEDIATED AND STRUCTURALLY STRATIFIED HEALTH SYSTEMS

DOI [https://doi.org/10.31435/ijitss.1\(49\).2026.5191](https://doi.org/10.31435/ijitss.1(49).2026.5191)

RECEIVED 17 January 2026

ACCEPTED 24 March 2026

PUBLISHED 26 March 2026

LICENSE



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CENTANAFADINE IN ATTENTION-DEFICIT/HYPERACTIVITY DISORDER: PHARMACOLOGICAL INNOVATION WITHIN DIGITALLY MEDIATED AND STRUCTURALLY STRATIFIED HEALTH SYSTEMS

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ABSTRACT

Background: Attention-deficit/hyperactivity disorder (ADHD) represents a substantial clinical and socioeconomic burden worldwide, with significant direct and indirect costs and marked heterogeneity in pharmacotherapy use across healthcare systems (Chhibber et al., 2021, Dodds et al., 2024, Li et al., 2026). Simultaneously, ADHD care is increasingly delivered within digitally mediated infrastructures, including telepsychiatry and remote service models (Hubley et al., 2016, Myers et al., 2015, Torous et al., 2025).

Objective: This review evaluates centanafadine sustained-release (SR) as a pharmacological innovation in ADHD and examines its clinical evidence within the context of digital transformation, health system governance, and equity in access to care.

Methodology: A structured narrative review was conducted using peer-reviewed PubMed-indexed studies published between 2013 and 2026. The evidence base includes randomized controlled trials and long-term safety data for centanafadine (Adler et al., 2022, Mattingly et al., 2025, Ward et al., 2025, Wigal et al., 2020), indirect comparative analyses (Schein et al., 2024b), and studies addressing economic burden, regional prescribing variation, telehealth implementation, and documented racial, ethnic, and socioeconomic disparities in ADHD care (Akmatov et al., 2021, Coker et al., 2016, Ferrin et al., 2025, Gage et al., 2025, Ko et al., 2023, McKenna et al., 2024, Pearce et al., 2024).

Results: Clinical trials demonstrate statistically significant reductions in ADHD symptom severity in adults and adolescents treated with centanafadine SR, with an acceptable safety and tolerability profile supported by long-term exposure data (Adler et al., 2022, Mattingly et al., 2025, Ward et al., 2025, Wigal et al., 2020). Indirect comparative evidence situates centanafadine within the nonstimulant treatment landscape (Schein et al., 2024b). At the system level, ADHD remains associated with economic burden and heterogeneous prescribing patterns (Akmatov et al., 2021, Chhibber et al., 2021, Li et al., 2026). Digital service models demonstrate feasibility and clinical effectiveness in ADHD care (Hubley et al., 2016, Myers et al., 2015, Kurokawa et al., 2024), yet disparities in telehealth access and broader structural inequities continue to shape treatment utilization (Coker et al., 2016, Gage et al., 2025, Pearce et al., 2024).

Conclusion: Centanafadine expands the nonstimulant therapeutic portfolio in ADHD, however, its population-level impact will depend on how effectively it is integrated within digitally enabled care pathways, reimbursement frameworks, and equity-oriented governance structures. The alignment of pharmacological innovation with responsible digital implementation strategies may determine whether therapeutic expansion contributes to reducing or perpetuating existing inequalities in ADHD care (Claire et al., 2024, McKenna et al., 2024).

KEYWORDS

Attention-Deficit/Hyperactivity Disorder, Centanafadine, Digital Health, Telepsychiatry, Health Systems Governance, Health Equity

CITATION

Karolina Krawczyk, Karolina Magda Leszczyńska, Anna Krzysztofik, Jeremi Leon Jasiński, Maciej Tomasz Wiczorek, Weronika Napierała, Aleksandra Maria Tomaszewska, Alicja Maria Mitan, Karolina Julia Hak, Kamila Teresa Kańska. (2026) Centanafadine in Attention-Deficit/Hyperactivity Disorder: Pharmacological Innovation Within Digitally Mediated and Structurally Stratified Health Systems. *International Journal of Innovative Technologies in Social Science*. 1(49). doi: 10.31435/ijitss.1(49).2026.5191

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1. Introduction

Attention-deficit/hyperactivity disorder (ADHD) constitutes not only a prevalent neurodevelopmental condition but also a significant systemic challenge for contemporary healthcare systems. Its long-term clinical, educational, and socioeconomic consequences generate substantial public health and economic burden, including both direct healthcare expenditures and indirect costs related to productivity loss, academic disruption, and caregiver strain (Chhibber et al., 2021; Dodds et al., 2024). These findings position ADHD within broader debates on health system sustainability and resource allocation, particularly in contexts characterized by constrained budgets and growing demand for mental health services (Chhibber et al., 2021; Dodds et al., 2024).

Pharmacotherapy remains a cornerstone of ADHD management. However, patterns of medication use vary considerably across countries and regions. Registry-based and cross-national analyses demonstrate substantial heterogeneity in prescribing prevalence and temporal trends, indicating that medication diffusion is shaped not solely by epidemiological need but also by reimbursement models, regulatory environments, service organization, and healthcare infrastructure (Akmatov et al., 2021; Hodgkins et al., 2013; Li et al., 2026; Rzeszutek & Wolańczyk, 2025). These patterns underscore that pharmacological innovation operates within complex socio-technical systems, where access and utilization are mediated by governance structures and policy frameworks rather than clinical efficacy alone (Akmatov et al., 2021; Li et al., 2026).

Simultaneously, mental healthcare systems are undergoing digital transformation. The expanding field of digital mental health, including telepsychiatry, remote monitoring, and technology-enabled service delivery, has altered how psychiatric assessment and treatment are accessed and delivered (Torous et al., 2025; Philippe et al., 2022). Telepsychiatry models have demonstrated feasibility and clinical effectiveness in mental health care, including ADHD-specific service delivery (Hubley et al., 2016; Myers et al., 2015). In pediatric populations, telehealth-based ADHD assessments have shown reliability when standardized rating instruments are administered remotely (Kurokawa et al., 2024). Surveys of caregivers further indicate growing acceptance of telehealth modalities in ADHD management (Galvin et al., 2024).

However, digital transformation does not inherently eliminate structural inequalities. Evidence from the United States indicates disparities in telemedicine use and reimbursement patterns across regions and populations (Gage et al., 2025). Rural disparities in telehealth access appear to reflect infrastructural and systemic barriers rather than unwillingness to engage with digital services (Ko et al., 2023). In low-income and rural youth populations, telepsychiatry has been proposed as a mechanism to accelerate access to mental health services, yet equity-oriented implementation remains essential (Sharma et al., 2025). These findings suggest that technological infrastructure itself becomes a determinant of access to pharmacotherapy.

Centanafadine sustained-release (SR) represents a novel nonstimulant pharmacological option for ADHD. Randomized phase 2 and phase 3 trials in adults have demonstrated statistically significant improvements in ADHD symptom severity compared with placebo, alongside an acceptable safety and tolerability profile (Adler et al., 2022; Wigal et al., 2020). A 52-week open-label study supports long-term tolerability in adult populations (Mattingly et al., 2025), and randomized evidence in adolescents demonstrates efficacy and safety in younger age groups (Ward et al., 2025). Indirect comparative analyses further situate centanafadine within the broader ADHD pharmacotherapy landscape (Schein et al., 2024).

Yet, the introduction of a novel pharmacological agent in the era of digital mental health raises questions that extend beyond clinical trial outcomes. If access to diagnosis, prescription, and follow-up increasingly occurs through digitally mediated systems, then the real-world impact of new therapies depends not only on efficacy and tolerability but also on digital infrastructure, reimbursement governance, and system responsiveness (Claire et al., 2024; Torous et al., 2025).

Moreover, documented disparities in ADHD diagnosis and pharmacotherapy further complicate the landscape of innovation. In the United States, racial and ethnic disparities in diagnosis and treatment persist across childhood and adolescence (Coker et al., 2016; Morgan et al., 2013; Yang et al., 2022). In European contexts, socioeconomic gradients influence symptom burden, diagnostic pathways, and medication use (Pearce et al., 2024). Cross-national and within-country variation in prescribing patterns further illustrates that therapeutic diffusion reflects policy and structural conditions rather than uniform clinical need (Akmatov et al., 2021; Li et al., 2026). In digitally transforming systems, such inequalities may be reshaped but not automatically resolved.

1.1 The Innovation–Equity Tension in Digitally Transforming Systems

While novel pharmacological agents expand therapeutic options, their introduction occurs within healthcare systems characterized by structural inequalities. Evidence from the United States demonstrates that children from minority racial and ethnic groups are less likely to receive ADHD diagnosis and pharmacotherapy compared with non-Hispanic White children, even after adjustment for symptom presentation (Coker et al., 2016; Morgan et al., 2013; Yang et al., 2022).

In European settings, socioeconomic inequalities influence ADHD symptoms, diagnostic processes, and medication use (Pearce et al., 2024). Cross-national analyses and regional data reveal substantial heterogeneity in management approaches across Europe and within countries such as Germany (Akmatov et al., 2021; Hodgkins et al., 2013; Li et al., 2026).

The expansion of telepsychiatry and digital mental health services introduces additional layers to this innovation - equity tension. Although telehealth models can enhance geographic reach (Hubley et al., 2016; Myers et al., 2015), disparities in digital access, infrastructure, and reimbursement may reproduce or shift existing inequalities (Gage et al., 2025; Ko et al., 2023). Thus, pharmacological innovation must be examined within digitally mediated care pathways rather than in isolation.

1.2 System-Level and Technological Determinants of Access

Barriers to ADHD treatment extend beyond diagnostic processes and include structural, financial, and organizational obstacles limiting sustained engagement with care (McKenna et al., 2024). Medication use trends demonstrate continued growth globally, yet uneven diffusion across regions (Rzeszutek & Wolańczyk, 2025; Li et al., 2026).

Medication adherence and persistence further influence real-world effectiveness. Evidence in children and adolescents indicates that treatment continuation is shaped by clinical factors, tolerability, and system-level support structures (Ferrin et al., 2025). In adults, patient preferences significantly influence therapeutic decision-making (Schein et al., 2024).

Digital health technologies may modify some access barriers by facilitating remote consultation, follow-up, and monitoring (Torous et al., 2025; Philippe et al., 2022). However, successful integration of pharmacotherapy within digital care models requires governance frameworks capable of incorporating real-world evidence into health technology assessment and reimbursement decisions (Claire et al., 2024).

1.3 Aim and Scope

Although clinical trials establish the efficacy and safety profile of centanafadine SR (Adler et al., 2022; Mattingly et al., 2025; Ward et al., 2025; Wigal et al., 2020), there remains a need to examine how such neuropharmacological innovations function within digitally transforming and structurally heterogeneous healthcare systems characterized by economic constraints and access inequalities (Chhibber et al., 2021; Dodds et al., 2024; McKenna et al., 2024).

This narrative review synthesizes clinical evidence on centanafadine in adults and adolescents while situating these findings within the broader context of digital mental health transformation, health system governance, and equity. By integrating data on economic burden (Chhibber et al., 2021; Dodds et al., 2024), regional prescribing patterns (Akmatov et al., 2021; Li et al., 2026), digital service delivery (Galvin et al., 2024; Kurokawa et al., 2024; Myers et al., 2015), adherence and patient preferences (Ferrin et al., 2025; Schein et al., 2024), health technology assessment (Claire et al., 2024), and documented disparities in diagnosis and treatment (Coker et al., 2016; Morgan et al., 2013; Pearce et al., 2024; Yang et al., 2022), this review evaluates whether centanafadine represents not only a therapeutic advancement but also a system-level innovation embedded in the digital transformation of ADHD care.

2. Methodology

2.1 Research Design

This study was conducted as a structured narrative review designed to examine centanafadine not solely as a pharmacological intervention but as a therapeutic innovation embedded within digitally transforming and structurally heterogeneous healthcare systems. The review integrates clinical trial data with evidence on health system organization, digital service delivery, health technology assessment, economic burden, and structural inequalities in ADHD care (Adler et al., 2022; Akmatov et al., 2021; Chhibber et al., 2021; Claire et al., 2024; Dodds et al., 2024; Galvin et al., 2024; Hodgkins et al., 2013; Kurokawa et al., 2024; Li et al., 2026; Mattingly et al., 2025; McKenna et al., 2024; Myers et al., 2015; Pearce et al., 2024; Philippe et al., 2022; Rzeszutek & Wolańczyk, 2025; Schein et al., 2024; Sharma et al., 2025; Torous et al., 2025; Ward et al., 2025; Wigal et al., 2020).

The methodological approach was grounded in a systems-oriented and technology-sensitive framework. Rather than evaluating centanafadine exclusively in terms of efficacy and tolerability, the analysis situates clinical evidence within broader socio-technical infrastructures, including telepsychiatry implementation, digital mental health integration, reimbursement governance, and equity-oriented health system design (Claire et al., 2024; Philippe et al., 2022; Torous et al., 2025).

2.2 Data Sources and Scope of Evidence

The review is based exclusively on peer-reviewed publications indexed in PubMed and published between 2013 and 2026. The evidence base encompasses clinical trials of centanafadine, population-level studies of ADHD pharmacotherapy, analyses of digital mental health delivery, and research addressing disparities and health system determinants (Adler et al., 2022; Akmatov et al., 2021; Chhibber et al., 2021; Claire et al., 2024; Coker et al., 2016; Dodds et al., 2024; Ferrin et al., 2025; Galvin et al., 2024; Gage et al., 2025; Hodgkins et al., 2013; Hubley et al., 2016; Ko et al., 2023; Kurokawa et al., 2024; Li et al., 2026; Mattingly et al., 2025; McKenna et al., 2024; Morgan et al., 2013; Myers et al., 2015; Pearce et al., 2024; Philippe et al., 2022; Rzeszutek & Wolańczyk, 2025; Schein et al., 2024; Sharma et al., 2025; Shende & Wagh, 2024; Torous et al., 2025; Ward et al., 2025; Wigal et al., 2020; Yang et al., 2022).

The selection includes:

- Phase 2 and Phase 3 randomized controlled trials evaluating efficacy and safety of centanafadine in adults (Adler et al., 2022; Wigal et al., 2020);
- Long-term open-label safety data (Mattingly et al., 2025);
- A randomized clinical trial in adolescents (Ward et al., 2025);
- A matching-adjusted indirect comparison situating centanafadine within the broader ADHD pharmacotherapy landscape (Schein et al., 2024);
- Systematic reviews addressing economic burden and healthcare utilization (Chhibber et al., 2021; Dodds et al., 2024);
- Studies examining medication adherence and patient preferences (Ferrin et al., 2025; Schein et al., 2024);
- Analyses of regional prescribing patterns and cross-national variation (Akmatov et al., 2021; Hodgkins et al., 2013; Li et al., 2026);
- Empirical research documenting racial, ethnic, and socioeconomic disparities in ADHD diagnosis and treatment (Coker et al., 2016; Morgan et al., 2013; Pearce et al., 2024; Yang et al., 2022);
- Research on telepsychiatry and digital mental health delivery models, including ADHD-specific applications (Galvin et al., 2024; Hubley et al., 2016; Kurokawa et al., 2024; Myers et al., 2015; Philippe et al., 2022; Torous et al., 2025);
- Studies addressing digital access disparities and telemedicine reimbursement structures (Gage et al., 2025; Ko et al., 2023; Sharma et al., 2025);
- Literature on real-world evidence and its role in health technology assessment and policy decision-making (Claire et al., 2024).

Only peer-reviewed studies were included. Editorials, case reports, and non-indexed grey literature were excluded to ensure methodological consistency.

2.3 Inclusion Criteria

To ensure conceptual coherence with the article's focus on innovation within digitally transforming systems, the following inclusion criteria were applied:

1. Studies directly evaluating centanafadine efficacy, safety, tolerability, or comparative positioning (Adler et al., 2022; Mattingly et al., 2025; Schein et al., 2024; Ward et al., 2025; Wigal et al., 2020);
2. Systematic reviews or population-based studies examining economic burden and healthcare utilization associated with ADHD (Chhibber et al., 2021; Dodds et al., 2024);
3. Research addressing adherence, treatment persistence, or patient preferences (Ferrin et al., 2025; Schein et al., 2024);
4. Population-level or registry-based studies investigating regional variation in pharmacotherapy and system-level diffusion patterns (Akmatov et al., 2021; Hodgkins et al., 2013; Li et al., 2026; Rzeszutek & Wolańczyk, 2025);
5. Empirical studies documenting racial, ethnic, or socioeconomic disparities in ADHD diagnosis and treatment (Coker et al., 2016; Morgan et al., 2013; Pearce et al., 2024; Yang et al., 2022);
6. Research examining telepsychiatry, digital mental health interventions, and technology-enabled ADHD care (Galvin et al., 2024; Hubley et al., 2016; Kurokawa et al., 2024; Myers et al., 2015; Philippe et al., 2022; Torous et al., 2025; Shende & Wagh, 2024);
7. Studies addressing digital access disparities and telemedicine governance (Gage et al., 2025; Ko et al., 2023; Sharma et al., 2025);
8. Literature exploring real-world evidence integration into health technology assessment and policy frameworks (Claire et al., 2024).

Studies not directly related to ADHD pharmacotherapy, digital mental health delivery, health system governance, or socioeconomic determinants of access were excluded.

2.4 Data Extraction and Analytical Framework

Data were extracted from each included study with attention to:

- Study design and population characteristics;
- Clinical outcomes (efficacy measures, safety, tolerability) where applicable (Adler et al., 2022; Mattingly et al., 2025; Ward et al., 2025; Wigal et al., 2020);
- Comparative effectiveness findings (Schein et al., 2024);
- Economic indicators and cost-related outcomes (Chhibber et al., 2021; Dodds et al., 2024);
- Measures of access, utilization, adherence, and persistence (Ferrin et al., 2025; McKenna et al., 2024; Schein et al., 2024);
- Evidence of regional variation, digital access inequalities, and structural disparities (Akmatov et al., 2021; Coker et al., 2016; Gage et al., 2025; Ko et al., 2023; Li et al., 2026; Morgan et al., 2013; Pearce et al., 2024; Yang et al., 2022);
- Evidence regarding telepsychiatry implementation, digital delivery models, and technology-enabled care pathways (Galvin et al., 2024; Hubley et al., 2016; Kurokawa et al., 2024; Myers et al., 2015; Philippe et al., 2022; Torous et al., 2025);
- Considerations relevant to real-world evidence and policy integration (Claire et al., 2024).

The synthesis follows a technology-informed systems framework integrating four interrelated dimensions:

1. Clinical innovation (efficacy, safety, comparative positioning);
2. Digital health infrastructure (telepsychiatry, remote assessment, digital delivery models);
3. Health system governance (reimbursement structures, regional variation, real-world evidence integration);
4. Equity and socioeconomic context (racial, ethnic, socioeconomic, and digital access disparities).

This structured approach enables evaluation of centanafadine as both a neuropharmacological development and a therapeutic innovation operating within digitally transforming health systems, with implications for governance, reimbursement policy, and equitable access to ADHD care.

3. Results

3.1 Clinical Evidence of Centanafadine as a Therapeutic Case Study

3.1.1 Therapeutic Positioning Within the ADHD Pharmacotherapy Landscape

Centanafadine sustained-release (SR) has been developed as a nonstimulant pharmacological intervention for ADHD, targeting core symptoms through modulation of monoaminergic neurotransmission implicated in attentional control and executive functioning (Adler et al., 2022; Wigal et al., 2020). Within contemporary ADHD treatment frameworks, pharmacotherapy remains central to symptom management. However, therapeutic options are generally categorized as stimulant or nonstimulant, each associated with distinct efficacy profiles, tolerability considerations, and clinical positioning (Schein et al., 2024b).

The introduction of centanafadine expands the nonstimulant segment of ADHD pharmacotherapy, potentially broadening therapeutic sequencing strategies, particularly in patients who do not tolerate or respond adequately to stimulant medications (Schein et al., 2024b). Its positioning is therefore clinically relevant not only from a symptom-reduction perspective but also within structured treatment algorithms shaped by reimbursement criteria and guideline recommendations (Schein et al., 2024b).

3.1.2 Phase 2 and Phase 3 Evidence in Adults

Phase 2 randomized, double-blind, placebo-controlled studies established initial evidence of dose-dependent efficacy of centanafadine SR in adults with ADHD, demonstrating statistically significant reductions in standardized ADHD symptom scores compared with placebo (Wigal et al., 2020). These studies supported sustained-release, once-daily administration and informed dose selection for subsequent confirmatory trials (Wigal et al., 2020).

Two multicenter, randomized, double-blind, placebo-controlled phase 3 trials further evaluated centanafadine SR in adult populations (Adler et al., 2022). In both trials, centanafadine was associated with statistically significant improvements in overall ADHD symptom severity relative to placebo, including improvements across inattention and hyperactivity/impulsivity domains (Adler et al., 2022). The consistency of findings across independent trials strengthens the evidentiary basis supporting clinical efficacy in adults (Adler et al., 2022).

Tolerability data from phase 2 and phase 3 investigations indicate that centanafadine was generally well tolerated, with adverse events aligned with its pharmacological profile and without identification of unexpected safety concerns (Adler et al., 2022; Wigal et al., 2020).

3.1.3 Long-Term Safety and Evidence in Adolescents

Given the chronic course of ADHD and the need for sustained treatment in many individuals, long-term safety data are clinically significant. A 52-week open-label study in adults indicated a stable and acceptable tolerability profile during extended treatment exposure (Mattingly et al., 2025). These findings provide additional context for long-term treatment in real-world clinical practice (Mattingly et al., 2025).

Beyond adult populations, a randomized clinical trial in adolescents showed statistically significant reductions in ADHD symptom severity relative to placebo, while maintaining a safety profile consistent with that observed in adults (Ward et al., 2025). The presence of efficacy and safety data across age groups suggests potential applicability within both adolescent and adult treatment pathways (Ward et al., 2025).

3.1.4 Comparative Effectiveness and System-Level Positioning

In the absence of direct head-to-head randomized trials, a matching-adjusted indirect comparison (MAIC) evaluated centanafadine relative to established ADHD pharmacotherapies, including lisdexamfetamine, atomoxetine, and viloxazine extended-release. Although indirect comparisons have methodological limitations, they provide information relevant to formulary placement and reimbursement decisions. In many healthcare systems, such decisions are guided by comparative effectiveness evidence (Schein et al., 2024b).

From a system perspective, such comparative positioning may influence therapeutic sequencing, payer decisions, and inclusion within national or regional formularies, thereby shaping real-world uptake beyond the confines of clinical trial settings (Schein et al., 2024b).

Table 1. Summary of Clinical Evidence for Centanafadine SR

Study (Ref.)	Population	Design	Key Clinical Findings	Main Conclusion
Wigal et al., 2020	Adults	Phase 2 RCT	Symptom reduction	Dose-dependent efficacy; acceptable tolerability
Adler et al., 2022	Adults	Phase 3 RCT (2 trials)	Symptom reduction	Significant improvement vs placebo; well tolerated
Mattingly et al., 2025	Adults	52-week open-label	Long-term safety	Stable tolerability over extended exposure
Ward et al., 2025	Adolescents	RCT	Symptom reduction	Efficacy confirmed; safety consistent with adults
Schein et al., 2024b	Adults	MAIC	Comparative efficacy	Positioned within nonstimulant landscape

3.2 Economic Burden and System-Level Implications

Beyond clinical symptom reduction, ADHD is associated with substantial direct and indirect economic burden. A global systematic review identified significant healthcare expenditures as well as productivity losses, educational disruption, and family-level impact (Chhibber et al., 2021).

Similarly, meta-analytic evidence indicates increased healthcare service utilization among children with ADHD compared with non-ADHD populations, contributing to elevated system-level costs (Dodds et al., 2024).

These findings highlight that therapeutic innovations must be considered not only in terms of individual efficacy but also in relation to broader system sustainability and long-term cost trajectories (Chhibber et al., 2021; Dodds et al., 2024).

3.3 Regional Variation in Pharmacotherapy and Digital Service Delivery

Regional variation in ADHD pharmacotherapy reflects structural determinants embedded within healthcare systems, rather than differences in clinical need alone. Registry-based data from Germany demonstrate significant secular trends and inter-regional variability in prescribing rates among children and adolescents, indicating that local practice cultures and health service organization influence medication use (Akmatov et al., 2021). Similarly, cross-national European analyses reveal substantial differences in ADHD medication utilization between 2010 and 2023, suggesting that regulatory frameworks and reimbursement models shape diffusion patterns (Li et al., 2026).

Broader European data further indicate that management approaches and prescribing behaviors vary across healthcare systems, reflecting differences in provider characteristics, service organization, and treatment pathways (Hodgkins et al., 2013). Global trends confirm increasing medication use overall, yet with persistent heterogeneity across regions and age groups (Rzeszutek & Wolańczyk, 2025).

Importantly, variation in pharmacotherapy adoption unfolds within increasingly digitized healthcare environments. Telehealth and telepsychiatry models have expanded access to mental health services, particularly in rural and underserved settings, potentially altering pathways to diagnosis and treatment initiation (Myers et al., 2015; Sharma et al., 2025; Shende & Wagh, 2024). Evidence suggests that telepsychiatry can produce clinical outcomes comparable to in-person care, supporting its role in routine ADHD management (Hubley et al., 2016; Myers et al., 2015).

However, disparities in telehealth utilization indicate that digital infrastructure does not automatically eliminate inequities. In the United States, telemedicine use and payment policies vary across regions and populations, with documented disparities in uptake between 2019 and 2023 (Gage et al., 2025). Rural disparities appear to be driven primarily by differential access rather than willingness to use telehealth services (Ko et al., 2023).

These findings suggest that the diffusion of new pharmacological therapies, including centanafadine, will likely be mediated not only by regulatory and reimbursement structures but also by the availability and equity of digital health infrastructure.

3.4 Access, Structural Inequalities, and Digital Mediation of Care

Barriers to ADHD treatment extend beyond diagnostic recognition and include organizational complexity, long waiting times, limited specialist availability, and financial constraints (McKenna et al., 2024). Such structural barriers may disproportionately affect socioeconomically disadvantaged populations (Pearce et al., 2024).

In the United States, racial and ethnic disparities in ADHD diagnosis and pharmacotherapy have been consistently documented, with minority children less likely to receive formal diagnosis or medication compared with non-Hispanic White peers (Coker et al., 2016; Morgan et al., 2013; Yang et al., 2022). These disparities persist even after adjustment for symptom presentation, suggesting systemic influences beyond clinical severity (Morgan et al., 2013).

Digital service delivery models introduce both opportunities and risks in this context. Telepsychiatry may mitigate geographic barriers and enhance access in underserved areas (Sharma et al., 2025; Myers et al., 2015). Survey data from caregivers indicate growing utilization of telehealth in ADHD management, reflecting acceptance of digital modalities within pediatric mental health care (Galvin et al., 2024).

At the same time, unequal access to broadband, digital literacy gaps, and differential reimbursement structures may reproduce or amplify existing inequities (Gage et al., 2025; Ko et al., 2023). Thus, pharmacological innovation such as centanafadine cannot be evaluated independently of the digital ecosystems through which diagnosis, follow-up, and medication management increasingly occur.

4. Discussion

4.1 Pharmacological Innovation in Digitally Transforming Systems

Centanafadine SR demonstrates clinically significant symptom reduction in adults and adolescents, supported by randomized controlled trials and long-term safety data (Adler et al., 2022; Mattingly et al., 2025; Ward et al., 2025; Wigal et al., 2020). From a clinical standpoint, these findings justify its positioning within the expanding nonstimulant segment of ADHD pharmacotherapy (Schein et al., 2024b).

However, clinical efficacy alone does not determine population-level impact. Evidence of substantial cross-national and regional variation in ADHD medication use demonstrates that pharmacotherapy adoption is shaped by healthcare organization, reimbursement structures, and regulatory frameworks (Akmatov et al., 2021; Hodgkins et al., 2013; Li et al., 2026). In contemporary healthcare environments, these structural determinants increasingly operate within digitally mediated service models.

Telepsychiatry and telehealth have expanded access to mental health care, particularly in rural and underserved settings, potentially altering diagnostic pathways and medication management processes (Hublely et al., 2016; Myers et al., 2015; Sharma et al., 2025; Shende & Wagh, 2024). Evidence suggests that telepsychiatry can achieve clinical outcomes comparable to in-person care, supporting its integration into routine ADHD management (Hublely et al., 2016; Myers et al., 2015).

In this context, centanafadine should be understood not only as a pharmacological innovation but as a therapy entering digitally transforming systems in which diagnosis, follow-up, and treatment continuation may be increasingly mediated through digital platforms.

4.2 Digital Infrastructure, Access, and Structural Inequality

While digital service delivery models may reduce geographic barriers, they do not automatically eliminate structural inequities. Disparities in telemedicine utilization and reimbursement policies in the United States demonstrate uneven uptake across regions and populations (Gage et al., 2025). Rural disparities appear to be driven primarily by differential access to infrastructure rather than reluctance to use telehealth services (Ko et al., 2023).

At the same time, longstanding racial and ethnic disparities in ADHD diagnosis and pharmacotherapy persist in the United States (Coker et al., 2016; Morgan et al., 2013; Yang et al., 2022), while socioeconomic gradients shape diagnosis and medication access in European contexts (Pearce et al., 2024). Structural barriers to service engagement, including organizational complexity and limited specialist availability, remain significant determinants of access (McKenna et al., 2024).

These findings indicate that digital transformation may either mitigate or reproduce existing inequities, depending on infrastructure availability, reimbursement design, and implementation strategy. The diffusion of new pharmacological agents such as centanafadine is therefore likely to be mediated by digital access patterns in addition to traditional regulatory and policy factors.

4.3 Real-World Evidence, HTA, and Governance of Innovation

In healthcare systems where reimbursement and formulary decisions are guided by comparative effectiveness assessments, indirect comparative evidence may influence coverage decisions (Schein et al., 2024b). However, long-term system integration increasingly depends on real-world data and health technology assessment (HTA) processes.

Advancing the use of real-world evidence (RWE) in HTA has been identified as a priority for evaluating the performance of therapies beyond controlled trial settings (Claire et al., 2024). Digital health records and telehealth platforms may facilitate the generation of real-world utilization and safety data, thereby enabling reimbursement assessment and post-marketing evaluation.

More broadly, the evolving field of digital mental health highlights the integration of smartphone-based tools, remote monitoring, and digital service platforms into psychiatric care delivery (Torous et al., 2025). Meta-review evidence suggests that digital mental health interventions can support service delivery and patient engagement, although implementation challenges persist (Philippe et al., 2022).

Within this governance landscape, centanafadine represents a case example of how pharmacological innovation interacts with digital ecosystems, HTA mechanisms, and real-world monitoring infrastructures.

4.4 Adherence, Personalization, and Digital Mediation

Medication adherence and persistence remain critical determinants of long-term effectiveness in ADHD management (Ferrin et al., 2025). In adults, treatment preferences influence therapeutic selection and may shape sustained engagement in care (Schein et al., 2024a).

Digital follow-up systems, telepsychiatry models, and remote monitoring tools may support continuity of care and shared decision-making processes, potentially enhancing treatment persistence within routine practice (Hubley et al., 2016; Myers et al., 2015; Philippe et al., 2022). However, such benefits presuppose equitable access to digital infrastructure.

Without targeted efforts to address structural barriers and socioeconomic inequalities, digital service delivery may fail to translate pharmacological innovation into equitable population-level benefit (McKenna et al., 2024; Pearce et al., 2024).

4.5 System Responsiveness and Responsible Diffusion

Evidence demonstrates that ADHD pharmacotherapy adoption varies substantially across regions and healthcare systems (Akmatov et al., 2021; Li et al., 2026; Rzeszutek & Wolańczyk, 2025). Such variation reflects the responsiveness of healthcare systems to innovation, shaped by regulatory thresholds, financing mechanisms, and service organization.

The introduction of centanafadine therefore presents not only a therapeutic development but also a governance challenge. Its long-term impact will depend on how effectively healthcare systems align clinical evidence, digital infrastructure, reimbursement policies, and equity-oriented monitoring strategies.

Innovation that is not accompanied by structural and digital inclusivity risks reinforcing existing gradients of inequality documented in ADHD diagnosis and treatment (Coker et al., 2016; Morgan et al., 2013; Pearce et al., 2024; Yang et al., 2022). Conversely, digitally enabled monitoring, real-world evaluation, and targeted policy design may support more equitable diffusion of new therapies.

4.6 Digital Transformation of ADHD Care Pathways

The delivery of ADHD care is increasingly mediated by digital infrastructures that reshape diagnostic pathways, treatment initiation, monitoring, and long-term follow-up. Traditional models of care have relied primarily on in-person specialist consultations and periodic clinical reassessment. In contrast, telepsychiatry and telehealth platforms now enable remote diagnostic evaluation, medication management, and follow-up across geographically dispersed populations (Hubley et al., 2016; Myers et al., 2015; Sharma et al., 2025; Shende & Wagh, 2024).

Evidence indicates that telepsychiatry can achieve clinical outcomes comparable to face-to-face care in ADHD management (Hubley et al., 2016; Myers et al., 2015). In pediatric populations, caregiver-reported data

demonstrate growing integration of telehealth into ADHD service delivery (Galvin et al., 2024). Furthermore, telepsychiatry-based assessment tools have demonstrated reliability in structured ADHD rating scale administration, supporting the feasibility of remote diagnostic processes (Kurokawa et al., 2024).

Beyond service delivery, digital mental health ecosystems increasingly incorporate mobile applications, remote monitoring tools, and data-driven platforms that extend psychiatric care beyond traditional clinical settings (Torous et al., 2025). Meta-review evidence suggests that digital mental health interventions can support service delivery and patient engagement, although implementation quality and contextual integration remain critical determinants of effectiveness (Philippe et al., 2022).

Within such digitally transforming care pathways, pharmacological therapies function as components of broader treatment ecosystems rather than isolated interventions. The integration of centanafadine into ADHD management may therefore occur alongside tele-follow-up systems, digitally mediated symptom monitoring, and real-world data capture infrastructures. Digital health records and telehealth platforms may facilitate the generation of real-world utilization and safety data, thereby supporting reimbursement decision-making and post-marketing evaluation (Claire et al., 2024).

Importantly, digital transformation does not inherently guarantee equitable diffusion of innovation. Disparities in telemedicine access and utilization demonstrate that digital infrastructures may reproduce existing socioeconomic and regional inequities if not accompanied by targeted policy measures (Gage et al., 2025; Ko et al., 2023). Consequently, the long-term impact of centanafadine will depend not only on clinical efficacy but also on how effectively digitally mediated care pathways are aligned with equity-oriented governance frameworks.

Table 2. System and Digital Determinants Influencing Implementation of Centanafadine

Domain	Evidence	Implementation Implication
Economic burden	Chhibber et al., 2021; Dodds et al., 2024	Need for scalable treatment models
Regional prescribing variation	Akmatov et al., 2021; Li et al., 2026;	Need for scalable treatment models
Racial/ethnic disparities (US)	Coker et al., 2016; Yang et al., 2022	Risk of unequal diffusion
Socioeconomic inequalities (Europe)	Pearce et al., 2024	SES-mediated access gradients
Structural service barriers	McKenna et al., 2024	Organizational constraints on access
Telepsychiatry effectiveness	Hubley et al., 2016; Myers et al., 2015	Digital models may expand reach
Telehealth disparities	Gage et al., 2025; Ko et al., 2023	Digital divide may shape access
Digital health & RWE	Torous et al., 2025; Claire et al., 2024	Data-driven governance potential

5. Conclusions

Centanafadine sustained-release (SR) represents a clinically validated nonstimulant pharmacological option for the treatment of attention-deficit/hyperactivity disorder (ADHD), supported by phase 2 and phase 3 randomized controlled trials in adults, confirmatory evidence in adolescents, and long-term safety data (Adler et al., 2022; Mattingly et al., 2025; Ward et al., 2025; Wigal et al., 2020). Indirect comparative analyses further position centanafadine within the contemporary ADHD pharmacotherapy landscape, informing its potential role in treatment sequencing and formulary consideration (Schein et al., 2024).

However, the relevance of centanafadine extends beyond its pharmacological profile. ADHD care is increasingly delivered within digitally mediated health systems incorporating telepsychiatry, remote monitoring, and real-world data infrastructures (Hubley et al., 2016; Myers et al., 2015; Torous et al., 2025).

Telehealth-based assessment models demonstrate feasibility and reliability in ADHD management (Kurokawa et al., 2024), while broader digital mental health interventions support service delivery and patient engagement across care settings (Philippe et al., 2022). Within this evolving technological landscape, pharmacotherapy functions as one component of an integrated care ecosystem rather than an isolated intervention.

At the same time, ADHD remains associated with substantial economic burden and marked heterogeneity in medication use across healthcare systems (Akmatov et al., 2021; Chhibber et al., 2021; Dodds et al., 2024; Li et al., 2026). Structural and organizational barriers continue to shape access to treatment (McKenna et al., 2024), and documented racial, ethnic, and socioeconomic disparities influence diagnostic and prescribing patterns (Coker et al., 2016; Morgan et al., 2013; Pearce et al., 2024; Yang et al., 2022). Importantly, disparities in telemedicine access indicate that digital transformation alone does not guarantee equitable diffusion of innovation (Gage et al., 2025; Ko et al., 2023).

The population-level impact of centanafadine will therefore depend not only on clinical efficacy but on how effectively it is embedded within digitally enabled care pathways, reimbursement frameworks, and equity-oriented governance structures. Digital health records and telehealth platforms may support the generation of real-world utilization and safety data relevant for reimbursement decision-making and post-marketing evaluation (Claire et al., 2024), yet such infrastructures must be aligned with policies that actively monitor access and utilization patterns.

Future research should prioritize real-world implementation studies examining how centanafadine is adopted within technology-enabled ADHD care models, including telepsychiatry-based prescribing, digitally supported adherence monitoring, and population-level equity outcomes. The integration of pharmacological innovation with responsible digital governance may ultimately determine whether therapeutic expansion contributes to narrowing or perpetuating existing inequalities in ADHD care (Akmatov et al., 2021; Coker et al., 2016; McKenna et al., 2024; Pearce et al., 2024).

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All authors have read and agreed to the published version of the manuscript.

Conflict of Interest Statement: The authors declare no conflicts of interest.

Declaration of the use of generative AI and AI-assisted technologies in the writing process: In preparing this work, the authors used ChatGPT for the purpose of improving language and readability. After using this tool, the authors reviewed and edited the content as needed and take full responsibility for the content of the publication.

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